UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

GIOVANNA BULOX, *et al.*, *Plaintiffs,*	§	
v.	§	Case No. 4:21-CV-02320
COOPERSURGICAL, INC., *et al.*, *Defendants.*	§	

ORDER ON PLAINTIFFS' *DAUBERT* MOTION FOR DR. GUPTA[1]

Before the Court is Plaintiffs' motion to exclude certain opinions offered by Defendants' fact and expert witness, Janesh K. Gupta, M.D., a clinical advisor and medical consultant for Defendants. ECF No. 132.[2] Plaintiffs argue that Dr. Gupta is not qualified to testify as an expert in this case, and his opinions are unreliable and unhelpful. ECF No. 132. Defendants respond that Dr. Gupta will not testify as to several of the objected-to topics, and on the rest, Plaintiffs' objections are best addressed via cross examination. ECF No. 142. Based on the briefing,[3] applicable law, and record, Plaintiffs' motion is denied because the arguments raised are suited for vigorous cross-examination at trial.

[1] The district judge to whom this case is assigned referred this motion in accordance with 28 U.S.C. § 636(b). Order, ECF No. 173.

[2] The Court notes that one unresolved issue impacting the viability of Plaintiffs' claims is federal preemption: the primary defense Defendants raise in their pending motions for summary judgment, *see* ECF Nos. 123, 124, 125, and ordered counsel to identify which motions to strike experts are relevant to resolution of that question. ECF No. 174. Plaintiffs identified this as one of the relevant motions. ECF No. 176.

[3] Defendants filed a response, ECF No. 142, and Plaintiffs filed a reply, ECF No. 154.

I. BACKGROUND

Defendants CooperSurgical, Inc., Femcare, Ltd., and Utah Medical Products, Inc. manufacture and distribute birth control devices called Filshie Clips. ECF No. 40 ¶ 19. Filshie Clips are 3-5 millimeters wide and are laparoscopically placed on the fallopian tubes. ECF No. 40 ¶ 21. Plaintiffs are individuals who had tubal ligation surgery in 2009 and 2010. ECF No. 40 ¶¶ 32, 46. In 2019, after years of experiencing pain, doctors removed two migrated Filshie Clips from Bulox's body, one in her intestinal wall. ECF No. 40 ¶¶ 36, 39, 42–45. Plaintiff Merlo had the same pain several years after her surgery, and in 2020, radiology showed the Filshie Clips migrated in her body. ECF No. 40 ¶¶ 50–51. An attempt to remove them laparoscopically was unsuccessful. Merlo still has displaced Filshie Clips in her body. ECF No. 40 ¶¶ 52–53. Plaintiffs sued Defendants for: (1) design defect; (2) manufacturing defect; (3) failure to warn; (4) strict liability; (5) negligence; (6) violation of consumer protection laws; (7) gross negligence; and (8) exemplary damages. ECF No. 40 at 17–32.

Defendants designated Dr. Gupta as a witness to assist their defense because he is "an experienced English OB/GYN who has used the Filshie Clip for decades, has both written and reviewed published literature on the Filshie Clip, [] specifically on [] Filshie Clip migration, and [] has since 2012 served as the independent medical consultant for Femcare Ltd.—reviewing complaints and assisting with risk reviews and other studies of the Filshie Clips." ECF No. 142 at 1–2. Plaintiffs seek to exclude

several of Dr. Gupta's opinions, namely any opinion regarding: (1) Bulox's medical condition; (2) Merlo's medical condition; (3) the design and/or manufacture of Filshie Clips; (4) the adequacy of warnings promulgated with Filshie Clips; and (5) FDA regulations or how they apply to Filshie Clips. ECF No. 132 at 4.

II. RELEVANT LAW

Federal Rule of Evidence 702 provides that "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

District courts act as the gatekeeper in making determinations as to the admissibility of expert testimony. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). As a preliminary matter, a district court must determine whether the proffered witness qualifies as an expert "by virtue of his knowledge, skill, experience, training, or education." *United States v. Cooks*, 589 F.3d 173, 179 (5th Cir. 2009) (quotation omitted). If the expert is qualified, the "overarching concern" becomes "whether the testimony is relevant and reliable." *Puga v. RCX*

Sols., Inc., 922 F.3d 285, 293 (5th Cir. 2019); *Bryant v. Intercontinental Terminals Co. LLC*, No. 4:19-CV-01460, 2023 WL 4108844, at *3 (S.D. Tex. June 21, 2023), *reconsideration denied*, No. 4:19-CV-01460, 2023 WL 4626676 (S.D. Tex. July 18, 2023) (quoting *Brown v. Illinois Cent. R. Co.*, 705 F.3d 531, 535 (5th Cir. 2013) (quoting *Daubert*, 509 U.S. at 589)). To be reliable, expert testimony must "be grounded in the methods and procedures of science and be more than unsupported speculation or subjective belief." *Johnson v. Arkema, Inc.*, 685 F.3d 452, 459 (5th Cir. 2012) (cleaned up). To be relevant, the expert's "reasoning or methodology [must] be properly applied to the facts in issue." *Id*. (quotation omitted).

"As a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility." *Puga*, 922 F.3d at 294. A district court's role under Rule 702 "is not to weigh the expert testimony to the point of supplanting the jury's fact-finding role—the court's role is limited to ensuring that the evidence in dispute is at least sufficiently reliable and relevant to the issue so that it is appropriate for the jury's consideration." *Id*. As the United States Supreme Court explained: "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596. "While the district court must act as a gatekeeper to exclude all irrelevant and unreliable expert testimony, 'the rejection of expert

testimony is the exception rather than the rule.'" *Puga*, 922 F.3d at 294 (quoting FED. R. EVID. 702 advisory committee's note to 2000 amendment).

The test of reliability is flexible—the Supreme Court has recognized the *Daubert* factors[4] "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *First v. AGCO Corp.*, No. 7:21-CV-0006-O, 2022 WL 1199211, at *1 (N.D. Tex. Mar. 8, 2022) (quoting *Kumho Tire*, 526 U.S. at 150). A district court has wide latitude in deciding *how* to determine reliability, just as it has considerable discretion with respect to the ultimate reliability determination. *Id.* (emphasis added) (citing *Kumho Tire*, 526 U.S. at 152).

The offering party must prove "'by a preponderance of the evidence that the testimony is reliable,' not that it is correct." *Bryant*, 2023 WL 4108844, at *3

[4] To meet this gatekeeping function, the Court "must make 'a preliminary assessment of whether the reasoning or methodology underlying the testimony is . . . valid and of whether that reasoning or methodology properly can be applied to the facts in issue.'" *Bryant*, 2023 WL 4108844, at *3 (quoting *Brown*, 705 F.3d at 535) (quoting *Daubert*, 509 U.S. at 592–93). *Daubert* lists five non-exclusive factors to consider when assessing the validity or reliability of expert testimony:

1. Whether the theory or technique has been tested;
2. Whether the theory or technique has been subjected to peer review and publication;
3. The known or potential rate of error of the method used;
4. The existence and maintenance of standards and controls in the methodology; and
5. Whether the theory or method has been generally accepted by the scientific community.

Daubert, 509 U.S. at 593–95. These factors are not necessarily limited to scientific evidence and apply to testimony offered by non-scientific experts, depending upon "the particular circumstances of the particular case at issue." *Kumho Tire Company, Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999).

(quoting *Swanston v. City of Plano, Tex.*, 2021 WL 327588, at *2 (E.D. Tex. Feb. 1, 2021) (quoting *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998))). The trial judge's discretion "will not be disturbed on appeal unless manifestly erroneous." *Id.* (quoting *Watkins v. Telsmith, Inc.*, 121 F.3d 984, 988 (5th Cir. 1997) (cleaned up)).

III. THE PARTIES RESOLVED SEVERAL ISSUES RAISED IN THE MOTION.

Plaintiffs argue that Dr. Gupta is unqualified to testify about: (1) the injuries sustained by Plaintiffs because he never treated or examined Plaintiffs and did not review their medical records; and (2) Defendants' FDA compliance because he does not practice medicine in the United States and possesses no knowledge of the FDA regulations or manufacturing or developing a medical device. ECF No. 132 at 10–11. Plaintiffs continue that Dr. Gupta's opinions are unreliable and unhelpful because he is not an FDA expert yet offers opinions regarding what is a "serious injury" and "reportable event" according to FDA standards, and he did not form his opinions according to objective independent methodology. ECF No. 132 at 13.

Defendants explain that they do not intend to offer several of the objected-to opinions, making them moot. ECF No. 142 at 4–7. First, "Dr. Gupta does not intend to provide any specific testimony on Plaintiffs." ECF No. 142 at 4. Second, Dr. Gupta provides no opinion on manufacturing or designing Filshie Clips, but rather he discusses how the design "physiologically accomplishes . . . female sterilization and result in migration," and he also points out that Plaintiffs' expert

has no experience in designing medical devices. ECF No. 142 at 4–5. Based on the Court's review, the above issues are denied as moot.

Third, Defendants have a separate FDA expert and do not intend to use Dr. Gupta as such—instead, Dr. Gupta discusses his *own* review of adverse event complaints as Defendants' independent medical consultant.[5] Dr. Gupta is a fact witness whose personal knowledge sometimes involved his expertise as a medical doctor. Defendants clarified that "Dr. Gupta's opinions . . . are really about his medical review of adverse event complaints in the context of FDA definitions—something he has been doing for the past twelve years and a practice that is explicitly permitted by FDA regulations." ECF No. 142 at 6. Plaintiffs assert that this clarification is insufficient because Dr. Gupta cannot offer the above testimony without also testifying about Defendants' FDA compliance. But that is the exact same testimony that they stated that they intend to elicit from him: "Plaintiffs intend to elicit testimony from Dr. Gupta regarding the Defendants' review and response to FDA complaints about migrated Filshie Clips. Dr. Gupta, in his role as a medical consultant, has relevant first-hand knowledge about these matters." ECF No. 132 at 18. This argument is insufficient for the exclusion of Dr. Gupta's testimony.[6]

---

[5] As an independent medical consultant, Dr. Gupta was asked to review complaints as a medical doctor and determine whether they met the FDA's definition of "serious injury" and whether the evidence "reasonably suggested" the Filshie Clip caused the injury. ECF No. 142 at 5.

[6] Moreover, Plaintiffs have failed to demonstrate why not practicing medicine in the United States means Dr. Gupta's testimony should be excluded – as a medical doctor with years of OB/GYN and Filshie Clip experience and familiarity with the FDA, he has sufficient qualifications to testify about the Filshie Clip, certain medical conditions, and his independent review of medical

The Court next considers Plaintiffs' remaining arguments: whether Dr. Gupta's opinions regarding adverse event complaints are the result of reliable methodology and whether Dr. Gupta's opinions that the Filshie Clip instructions for use ("IFU") are based on accurate and reliable data is unreliable and unsupported.

IV. PLAINTIFFS FAIL TO CARRY THEIR BURDEN TO EXCLUDE DR. GUPTA'S TESTIMONY.

A. Dr. Gupta May Testify About Reviewing Adverse Event Complaints.

Plaintiffs argue that Dr. Gupta's opinions regarding his review of reportable events are not backed by any independent methodology and therefore should be excluded. They argue that because Dr. Gupta lacks knowledge of the FDA and did not conduct independent research, he "relied only on his subjective interpretation of a definition of 'serious injury' provided to him by Femcare [] to make his determinations regarding serious injuries/reportable events," which led to inconsistent findings. ECF No. 132 at 13–14. Plaintiffs also argue that Dr. Gupta rejects medical reports and makes unfounded assumptions to discount patient reports of migration. ECF No. 132 at 14. Defendants respond that "Dr. Gupta [] applied his medical education and experience to review the complaints and make a judgment about their reportability in light of the FDA definitions of a serious injury and connection to a medical device. This is something he has been doing in practice for

---

complaints under the FDA regulations. Whether he practices in the United States might be relevant to Plaintiffs' cross examination, but Plaintiffs have not explained how it is grounds for his exclusion.

12 years, and there can be no question that he applies the same process used in practice in his report." ECF No. 142 at 9.

In his report, Dr. Gupta gives a detailed overview of his extensive medical experience and experience as a reviewer, ECF No. 142-1 at 3–4, and of the applicable FDA regulations, ECF No. 142-1 at 13. Dr. Gupta then explains his method for reviewing these complaints:

> when I review complaints, the key factors for me are (i) ascertaining whether there was a serious injury in accordance to the regulatory body definitions, and (ii) then determining whether there is a reasonable suggestion that the product may have caused the injury. The FDA provides the above definition of a serious injury, which makes that determination a fairly plain and straightforward one. But determining whether there is a reasonable suggestion of causation requires medical and physiological knowledge, familiarity with the literature, and understanding of the device.

ECF No. 142-1 at 14. Dr. Gupta then goes a step further, explaining that long-lasting chronic pain, the most common complaint with Filshie Clip migration, requires additional review due to the complexity of pain in the body, which for him, includes searching for additional physiological evidence in the medical history suggesting that the device caused or contributed to the reported problem. ECF No. 142-1 at 14.

Plaintiffs' arguments are insufficient to exclude Dr. Gupta's testimony as unreliable. The above report excerpts demonstrate sufficient methodology to admit his testimony. Unlike Plaintiffs' contentions, Dr. Gupta has adequate knowledge of the applicable FDA regulations and has educated himself independently of Femcare's provided material, citing to a wide body of literature in the field of chronic

pelvic pain. ECF No. 142-1 at 14.[7] Furthermore, "[a]s a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility and should be left for the jury's consideration." *McNees v. Ramirez*, No. CV H-17-3815, 2018 WL 8755882, at *2 (S.D. Tex. Dec. 7, 2018) (quoting *Primrose Operating Co. v. Nat'l Am. Ins. Co.*, 382 F.3d 546, 562 (5th Cir. 2004)). Counsel will have ample opportunity to conduct cross-examination and present contrary evidence to attack Dr. Gupta's conclusions. *See Daubert*, 509 U.S. at 596.

Plaintiffs' arguments largely relate to the bases of Dr. Gupta's review decisions, not the underlying methodology, and are therefore more suitable for cross examination. *See Roake v. Brumley*, No. CV 24-517-JWD-SDJ, 2024 WL 4751509, at *7 (M.D. La. Nov. 12, 2024) ("[m]atters left for the jury's consideration include the alleged miscalculations, erroneous assumptions, and inconsistencies that plaintiffs object to.") (quoting *Imperial Trading Co. v. Travelers Prop. Cas. Co. of Am.*, No. 06-4262, 2009 WL 2356292 at *3 (E.D. La. July 28, 2009) (citing *Southwire Co. v. J.P. Morgan Chase & Co.*, 528 F. Supp. 2d 908, 935 (W.D. Wis. 2007) ("the alleged errors and inconsistencies are grounds for impeaching the credibility of the experts and the reliability of their ultimate findings; however,

[7] Again, Plaintiffs seek to both elicit and exclude the same testimony from Dr. Gupta: his review of patient complaints related to clip migration. As discussed above, that Plaintiffs seek to cross examine Dr. Gupta on these same grounds regarding his personal experience with FDA review is indicative that these are not suitable *Daubert* arguments.

mistakes and miscalculations are not grounds for excluding evidence.") (citing *Daubert*, 509 U.S. at 596))).

B. Dr. Gupta May Testify About Filshie Clip Warnings.

Next, Plaintiffs contend that Dr. Gupta's opinions that the Filshie Clip instructions for use ("IFU") are based on accurate and reliable data is unreliable and unsupported because these opinions are "based on his own erroneous understanding of the language included in the documents and a rate of incidence (0.13%) provided to him by Defendants and not based on any peer-reviewed science or accepted medical principles." ECF No. 132 at 17.

Defendants respond that "[w]ith regard to the warnings in Filshie Clip IFUs, Dr. Gupta has employed his education and experience as a clinical expert who has implanted Filshie Clips for decades and counseled countless patients on the procedure. He also employs his own research, writing, and review of literature in reviewing the warnings for Filshie Clips to come to a conclusion as to whether they adequately warn of clip migration. The warnings for Filshie Clips are found in the IFUs, and as a doctor-implanted device, those IFUs will only be read by an implanting physician. Thus, Dr. Gupta possesses the knowledge and experience to opine on their adequacy." ECF No. 142 at 9.

The parties disagree on the underlying facts of Dr. Gupta's opinion that the Filshie Clip IFUs are based on accurate and reliable data. "It is not the role of the court to decide whether an expert's opinions are correct or, in the case of competing

and conflicting expert opinions, which one is right or even which one has greater support." *Roake*, 2024 WL 4751509, at *7. "[B]y deciding the disputed facts, the jury can decide which side's experts to credit." *Id.* (quoting Advisory Committee Note to the 2000 amendment to Rule 702, quoting *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 744 (3d Cir. 1994)). Without deciding the correctness of Dr. Gupta's opinion, the Court finds that his opinion is reliable: Dr. Gupta has extensive experience with implanting Filshie Clips and reviewing the IFUs—his testimony is based on this experience.

IV. CONCLUSION

Therefore, Plaintiffs' motion to limit Dr. Gupta's testimony, ECF No. 132, is **DENIED**.

It is so ORDERED.

Signed on February 27, 2025, at Houston, Texas.

Dena Palermo

Dena Hanovice Palermo
United States Magistrate Judge